

Serial No.: 10/663,265
Filed: September 16, 2003
AMENDMENT AND RESPONSE TO OFFICE ACTION

In the Claims

1.-2. (Cancelled)

3. (CURRENTLY AMENDED) A system composition for delivery of a gene naked DNA to a tissue site of a mammalian subject, the system composition comprising a polymeric matrix and an effective amount of naked DNA dispersed within the polymeric matrix.

wherein the polymeric matrix being dissolvable in a volatile organic solvent,
wherein said polymeric matrix is formed of a polymer selected from the group consisting

of synthetic polymers, synthetically polymerized polysaccharides, synthetically
polymerized proteins, chemically synthesized polymers, chemically synthesized
polysaccharides, and chemically synthesized proteins, wherein

a) — wherein the DNA contains a gene operatively linked to a promoter, the nucleotide
sequence of said gene being greater than 30 nucleotides in length;

b) — the polymeric matrix is and is in a form selected from the group consisting of
stents, coatings, slabs, gels and films; and

c) — wherein the naked DNA is loaded into the polymeric matrix at a concentration
between about 0.01 and 90% and is released or diffuses from the polymeric matrix.

4. (CURRENTLY AMENDED) The system composition of claim 3, wherein said system the composition can be implanted into a mammal.

5. (CURRENTLY AMENDED) The system composition of claim 3, wherein the polymeric matrix comprises a polymer selected from the group consisting of polymers of lactic acid and glycolic acid, polyanhydrides, poly(ortho)csters, and poly(caprolactone).

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6. (CURRENTLY AMENDED) The system composition of claim 3, wherein the polymeric matrix is biodegradable.
7. (CURRENTLY AMENDED) The system composition of claim 3, wherein the polymeric matrix is non-biodegradable.
8. (CURRENTLY AMENDED) The system composition of claim 3, wherein the polymeric matrix contains sufficient naked DNA such that the naked DNA can be released from said system released gene for at least three months.
9. (CURRENTLY AMENDED) The system composition of claim 3, wherein approximately 0.1-90% by weight of naked DNA is loaded into the polymeric matrix the gene encodes a protein.
10. (CURRENTLY AMENDED) The system composition of claim 3, wherein the naked DNA gene comprises supercoiled DNA, circular DNA, or a combination thereof.
11. (CURRENTLY AMENDED) The system composition of claim 3, wherein the naked DNA gene is greater than 100 nucleotides in length.
12. (CURRENTLY AMENDED) The system composition of claim 3, wherein the polymeric matrix is bioadhesive.
13. (CURRENTLY AMENDED) The system composition of claim 3, wherein the system further comprises compounds inhibiting inflammation due to the polymeric matrix, compounds increasing inflammation due to the polymeric matrix, antiinflammatories, or inhibitors of cytokines.
14. (CURRENTLY AMENDED) The system composition of claim 3, wherein the effective amount of naked DNA gene dispersed within the polymeric matrix is greater than 20 μ g.

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15. (CURRENTLY AMENDED) A method for delivery of naked DNA a gene, the method comprising implanting the system of claim 4 into the mammalian subject and allowing the naked DNA to be under conditions where the gene is released from or to diffuse is diffused from the polymeric matrix.

16. (CURRENTLY AMENDED) The method of claim 15, wherein the polymeric matrix is formed prior to implantation into the mammalian subject.

17. (CURRENTLY AMENDED) The method of claim 15, wherein the polymeric matrix is formed after implantation into the mammalian subject.

18. (CANCELLED)